IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KRANTHI GORLAMARI, Individually and on Behalf of All Others Similarly Situated, ***Plaintiff*,** ***v.*** **VERRICA PHARMACEUTICALS, INC., TED WHITE, P. TERENCE KOHLER JR. and A. BRIAN DAVIS,** ***Defendants*.**	**Civil Action** **No. 22-cv-2226**

MEMORANDUM OPINION

GOLDBERG, J. **January 11, 2024**

Plaintiff Kranthi Gorlamari ("Plaintiff") has filed this putative class action for securities fraud against Verrica Pharmaceuticals, Inc. ("Verrica"), and three of its executives: CEO Ted White, CFO P. Terence Kohler, Jr., and former CFO A. Brian Davis. Plaintiff alleges that Defendants concealed certain obstacles that prevented Verrica from obtaining approval from the Food and Drug Administration (FDA) of its largest product, causing Verrica's stock to remain artificially high and harming investors such as Plaintiff.

Defendants have moved to dismiss Plaintiff's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Because this is a securities fraud putative class action, examination of Plaintiff's complaint is subject to the heightened pleading standard of the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u-4(b). Defendants argue that the complaint should be dismissed for failure to meet this standard and because the complaint fails to plausibly

allege the elements of securities fraud. For the reasons that follow, I will grant Defendants' motion in part, deny it in part, and provide Plaintiff leave to replead.

I. FACTS

The following facts are taken from Plaintiff's amended complaint.

A. Verrica's Product

In the spring of 2021, Verrica was seeking to market a product called "VP-102," which was a drug-device combination for the treatment of molluscum, a skin disease. Verrica devoted "substantially all its financial resources and efforts to the development of" VP-102. (Am. Compl. ¶¶ 31-32.)

To be a viable product, VP-102 would require FDA approval. Verrica planned to have VP-102 manufactured by a contract manufacturer called Sterling Pharmaceutical Services, LLC ("Sterling"). In reviewing a new drug application (NDA), it was the FDA's practice to inspect manufacturing facilities to determine whether those facilities complied with FDA regulations known as "current good manufacturing practices" (cGMP). The product could not be approved unless the manufacturing facility was in compliance with cGMP. (Id. ¶¶ 42, 45-47.)

B. May 2021 FDA Inspection of Sterling

On April 13, 2021, Verrica's CEO, Defendant Ted White, announced at a conference that the FDA would inspect two contract manufacturing facilities, Sterling and one other, as part of the approval process for VP-102. (Am. Compl. ¶ 65.)

From May 3 to 14, 2021, the FDA inspected Sterling. (Id. ¶ 7.) At the end of that inspection, the FDA provided Sterling four observations of noncompliance with cGMP: (1) "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and/or followed"; (2) "Aseptic processing areas are deficient regarding the

system for monitoring environmental conditions"; (3) "Written records of investigations into unexplained discrepancies and failures of a batch or any of its components to meet specifications do not always include the conclusions and follow-up"; and (4) "The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed." (Id. ¶ 88.)

None of the FDA's four observations are alleged to have concerned production of VP-102 specifically, as VP-102 is not a sterile product. However, the FDA's observations did concern the facility in which VP-102 was manufactured (i.e. Sterling), and, as Plaintiff alleges, the "facility" itself was required to be in compliance with cGMP before the product would be approved. (Id. ¶ 47.)

The FDA communicated its four observations of noncompliance to Sterling in a document titled "Form 483." (Id. ¶ 88.) "A Form 483 documents conditions and practices discovered during an FDA inspection of drug manufacturing facilities that render the facilities out of compliance with cGMP." (Id. ¶ 7.) It is a form of "interim feedback" that lists "'significant conditions' that may indicate a drug is being prepared in ways that do not comply with FDA regulations," making "the company … responsible for taking corrective action to address any significant conditions identified." Schaeffer v. Nabriva Therapeutics plc, No. 19-cv-4183, 2020 WL 7701463, at *2 (S.D.N.Y. Apr. 28, 2020).

According to Plaintiff, "Defendants immediately knew that the May 2021 Sterling Inspection had taken place and had concluded with the issuance of a Form 483." (Am. Compl. ¶ 8.) Plaintiff bases this allegation on the following facts:

(a) "A former employee of Verrica ..., who was interviewed as part of Lead Counsel's investigation, recalled discussing the Form 483 during a mid-May 2021 meeting … ." (Id.)

(b) "Verrica personnel and [its] outside consultants … were[] on-site during the inspection." (Id.)

Plaintiff also alleges, based on information from the former employee, that "those present in the mid-May 2021 meeting acknowledged that receipt of the Form 483 would delay the launch of VP-102." (Id. ¶ 8.)

C. Verrica's Statements About the May 2021 Inspection of Sterling

1. May 19, 2021 ("we fully anticipate")

On May 19, 2021 (five days after the FDA finished inspecting Sterling and issued observations of noncompliance on Form 483), Verrica held a conference with institutional investors. Verrica's CEO, Ted White, answered a question as follows:

> DAN BUSBY: … With your PDUFA date[1] right around the corner, I know there's been some focus on the FDA inspection that's required and whether the agency will be able to get into that facility or two facilities[2] on time. Can you provide us with an update on where you stand in that process? And I know FDA introduced some new inspection-related guidance a couple days ago. Does that affect you at all?
>
> TED WHITE: Well, obviously it's a concern because, to your point, the FDA did put out guidance about the inspections. My concern is the backlog of inspections, they've never really addressed that. But we fully anticipate that we'll have our inspections take place according to plan, and we have not been notified otherwise.

(Am. Compl. ¶ 108 (emphasis added in complaint deleted).)

2. May 28, 2021 ("the FDA has recently completed")

On May 28, 2021, Verrica published a press release stating that the FDA had extended the goal date for acting on Verrica's new drug application from July 13, 2021 to September 23, 2021. The complaint does not allege why the goal date was extended or that the extension was related to observed problems at the Sterling facility. In that press release, CEO Ted White was quoted as

[1] This is the date by which the FDA plans to act on a new drug application.

[2] The FDA planned to inspect Sterling and another facility (called PPS). This case is only about Sterling, but the fact that there were two required inspections is relevant to interpreting Verrica's public statements.

stating: "Importantly, the FDA has recently completed one of the two pre-approval inspections required for approval." (Am. Compl. ¶ 67.)

3. June 2, 2021 ("more time to … complete one inspection")

On June 2, 2021, at a conference, CEO Ted White stated:

> We resubmitted the NDA 5 months later in December of 2020. We received acceptance from the agency in early 2021. We received a PDUFA goal date of June 23 of this year, and now that has been extended by 3 months. So, our new PDUFA goal date is September 23 to give the agency more time to review data and complete one inspection at one of our facilities.

(Am. Compl. ¶ 111 (emphasis added in complaint deleted).) The complaint does not clarify whether "one of our facilities" referred to Sterling or PPS.

D. September 2021 Application Denial and Verrica's Statements About It

On September 20, 2021, Verrica announced that the FDA had issued a letter, called a "complete response letter" (CRL), that the application for VP-102 would not be granted in its present form—essentially a denial. (Am. Compl. ¶ 68.) "Verrica explained that '[a]ccording to the CRL, the FDA has identified deficiencies at a facility of a contract manufacturing organization (CMO), which are not specifically related to the manufacturing of VP-102 but instead raise general quality issues at the facility.'" (Id.) The announcement continued:

> At no time prior to the CRL was the Company notified by the FDA of any deficiencies at the CMO[3] related specifically to the manufacturing of VP-102 or that their general investigation of the facility would have any impact on the Company's NDA. More importantly, the FDA did not identify any clinical, safety or product specific Chemistry, Manufacturing, and Controls (CMC) deficiencies related to VP-102.
>
> The Company understands from the CMO that it has implemented corrective actions to address the Agency's concerns and the CMO has advised Verrica that it is expecting a satisfactory resolution of the facility's identified deficiencies from the FDA within the next 30 business days. During this timeframe, the Company will engage with the Agency to demonstrate that the Company's good

[3] "Contract manufacturing organization"—i.e., Sterling.

> manufacturing practices, controls and processes ensure that any deficiencies at the CMO do not impact the efficacy, safety or quality of VP-102.

(Id. ¶ 69.)

Following this announcement, Verrica's stock fell 8.3%. (Id. ¶ 6.)

E. November 2021 "Voluntary Action Indicated" Outcome and Verrica's Statements About It

As alleged in Plaintiff's complaint, there are three possible outcomes to an FDA inspection:

- "No action indicated" (NAI), "which means no objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further regulatory action)";
- "Voluntary action indicated" (VAI), "which means objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action";
- "Official action indicated" (OAI), "which means regulatory and/or administrative actions will be recommended." (Am. Compl. ¶ 53.)

On November 12, 2021, Verrica issued a press release stating that the inspection at Sterling had been classified "voluntary action indicated":

> On November 5, 2021, Verrica was notified that the inspection of the CMO has been classified as "voluntary action indicated" ("VAI"), is now closed and that the VAI classification will not directly negatively impact FDA's assessment of the Company's NDA regarding this CMO. With the satisfactory resolution of the facility inspection, Verrica has engaged the FDA to determine the next steps toward the potential approval of VP-102 for the treatment of molluscum.

(Id. ¶ 116 (emphasis added in complaint deleted).)

On November 29, 2021, Verrica issued a press release that it had resubmitted its application for VP-102, stating that "[t]he resubmission addresses the successful resolution of inspection deficiencies identified at a contract manufacturing organization (CMO) [i.e. Sterling] in the CRL [i.e. the letter denying Verrica's previous application]." (Id. ¶ 118 (emphasis added in complaint deleted).)

The complaint does not allege what occurred to "successfully resolve" the cGMP violations at Sterling. However, the complaint does quote Verrica's press release stating that Verrica "understands from the CMO [i.e. Sterling] that it has implemented corrective actions." (Id. ¶ 118.)

F. February 2022 FDA Inspection

The complaint alleges that the FDA inspected Sterling a second time from February 7 to 18, 2022. This inspection again resulted in observations of noncompliance with cGMP, contained in another Form 483: (1) "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process"; (2) "The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed"; (3) "There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed"; and (4) "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed." (Am. Compl. ¶ 92.) Again, the complaint does not allege that these violations concerned the production of VP-102 specifically, but does allege that the facility had to be in compliance for a drug to be approved. (Id. ¶ 47.)

Plaintiff does not allege facts directly showing that Defendants were aware of the February 2022 inspection or its outcome. Instead, Plaintiff argues that knowledge can be inferred because "Defendants were on notice that any reinspection of Sterling and the FDA's observation were of critical importance to the approval of Verrica's resubmitted NDA for VP-102." (Am. Compl. ¶ 107.) Plaintiff also references generally Verrica's "Person in Plant" policy and FDA guidance encouraging contract manufacturers to "communicat[e] inspection observations." (Am. Compl. ¶¶ 97-98.)

G. Spring 2022 Statements in Verrica's SEC Filings

1. March 2, 2022 10-K

Plaintiff's complaint notes that on March 2, 2022, Verrica stated the following in a public securities filing signed by White and Kohler:

> On November 5, 2021, we were notified that the inspection of the CMO that had been classified as "voluntary action indicated", or VAI, is now closed and that the VAI classification would not directly negatively impact FDA's assessment of our NDA regarding this CMO. **With the satisfactory resolution of the facility inspection**, we resubmitted the NDA for the approval of VP-102 for the treatment of molluscum on November 29, 2021. The resubmission was limited to those sections and elements of the NDA that were identified as deficiencies in the CRL issued by the FDA in September 2021. **The resubmission addressed the successful resolution of inspection deficiencies identified at the CMO in the CRL**, as well as the recommendations included in the General Advice Letter received from the FDA that relate to VP-102's user interface. On December 15, 2021 the FDA accepted our NDA resubmission for VP-102 and assigned a new PDUFA date of May 24, 2022.

(Am. Compl. ¶ 121 (emphasis added in complaint).)

2. April 14, 2022 Conference

At an April 14, 2022 conference, Verrica CEO White stated the following:

> And then the [November 2021] CRL was totally unrelated to VP-102/Ycanth altogether. This was at one of our contract manufacturers Sterling Pharmaceutical Services in Dupo Illinois. They had just gone through a general inspection from the agency. They had 483 observations that had not been addressed at the time when they were doing our review.
>
> Now, the 483 that the manufacturer received were all on the aseptic sterile side.… Our product is not sterile and wasn't even on the same side of the building. So that was the [November 2021] CRL. And what we've done, just to ensure that everything is ready to go. We hired Jeff Yuen & Associates who is a former FDA inspector, as well as Greenleaf. And we had them … go out and do mock inspections at all of our CMO facilities to ensure that all our CMOs were inspection ready.

(Am. Compl. ¶ 124.) White was then asked, "[G]iven that in the last review cycle, like you said the CRL issues were minor and not really associated with the actual product, I guess we should

feel pretty confident that we should see an approval here in late May?" to which he responded: "From your lips to God's ears. Yes, I am very optimistic." (Am. Compl. ¶ 125.)

3. May 9, 2022 10-Q

On May 9, 2022, Verrica stated in another public securities filing, signed by White and Kohler:

> On November 5, 2021, we were notified that the inspection of the CMO has been classified as "voluntary action indicated", or VAI, is now closed and that the VAI classification will not directly negatively impact FDA's assessment of our NDA regarding this CMO. **With the satisfactory resolution of the facility inspection**, we resubmitted the NDA for the approval of VP-102 for the treatment of molluscum on November 29, 2021. The resubmission was limited to those sections and elements of the NDA that were identified as deficiencies in the CRL issued by the FDA in September 2021. On December 15, 2021 the FDA accepted our NDA resubmission for VP-102 and assigned a new PDUFA goal date of May 24, 2022.

(Am. Compl. ¶ 127 (emphasis added in complaint).)

H. Sterling's OAI Classification and Denial

On May 20, 2022, Verrica learned that Sterling's February 2022 FDA inspection had been classified "official action indicated" (OAI), the most severe classification. (Am. Compl. ¶ 93.) On May 24, 2022, Verrica announced a second CRL (i.e. denial) of its application for VP-102, and disclosed that the reason was Sterling's OAI classification. Verrica's stock price then fell significantly. (Id. ¶¶ 78-79.)

Based on these facts, Plaintiff alleges that he and others were defrauded into believing that barriers to approval of VP-102 involving quality issues at Sterling did not exist, causing Verrica's stock price to remain artificially high until these misstatements were corrected.

II. LEGAL STANDARD

Analysis of Plaintiff's complaint is governed both by the usual "plausibility" standard under Rule 8(a) as well as the heightened pleading standards under Rule 9(b) and the Private Securities Litigation Reform Act (PSLRA).

First, to survive a motion to dismiss pursuant to Rule 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). Conclusory allegations do not suffice. Id. Twombly and Iqbal's plausibility standard requires more than a "sheer possibility that a defendant has acted unlawfully." Id. Plausibility requires "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary elements of a claim." Phillips v. Cty. Of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008).

To determine the sufficiency of a complaint under Twombly and Iqbal, a court must (1) "tak[e] note of the elements a plaintiff must plead to state a claim"; (2) identify the allegations that are not entitled to the assumption of truth because they are no more than conclusions; and (3) "where there are well-pleaded factual allegations, … assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." Burtch v. Millberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011). Courts must construe the allegations in a complaint "in the light most favorable to the plaintiff." Id. at 220.

When deciding a motion to dismiss, "courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014).

In addition, the PSLRA and Rule 9(b) impose two requirements on a complaint pleading securities fraud. First, false statements must be alleged with "particularity." Tellabs, Inc. v. Makor

Issues & Rts., Ltd., 551 U.S. 308, 313 (2007). This standard requires the plaintiff to allege "all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294, 307 (3d Cir. 2016).

Second, the inference of scienter (i.e., conscious wrongdoing) must be more than plausible: it must be "strong." 15 U.S.C. § 78u-4(b)(2)(A). A strong inference is one that is "cogent and compelling," "strong in light of other explanations," and "at least as compelling as any opposing inference one could draw from the facts alleged." Id. at 324. "But a plaintiff does not need to come forward with 'smoking-gun' evidence to meet the PSLRA's pleading requirements. Rather, in conducting the scienter analysis, courts must analyze the complaint holistically to determine whether its allegations, 'taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" In re Hertz Glob. Holdings, Inc., 905 F.3d 106, 114 (3d Cir. 2018) (citation omitted) (quoting Tellabs, 551 U.S. at 323).

The "strong inference" standard only applies to the element of scienter, and does not apply to the element of falsity. See 15 U.S.C. § 78u-4(b)(2). Nevertheless, allegations supporting falsity are relevant to the strong inference standard because a defendant is less likely to realize the falsity of a statement that might plausibly be true. See Anderson v. Stonemor Partners, L.P., 296 F. Supp. 3d 693, 704 (E.D. Pa. 2017). Thus, where the inference of falsity is weak, more will be required to support the requisite strong inference of scienter. See id.

III. DISCUSSION

"Together, § 10(b) [of the Exchange Act] and [SEC] Rule 10b-5 imply a private cause of action for securities fraud. … That claim has six elements: (i) a misrepresentation or omission of

material fact; (ii) scienter; (iii) a connection with the purchase or sale of a security; (iv) reliance; (v) economic loss; and (vi) loss causation." City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc., 70 F.4th 668, 679 (3d Cir. 2023). Defendants assert that Plaintiff's complaint should be dismissed for failure to sufficiently plead falsity, scienter, and loss causation under the pleading standards set out above.

A. Falsity and Scienter as to Each Alleged Misstatement

Plaintiff alleges four separate categories of statements that he contends were fraudulently made: (1) White's May-June 2021 statements about the Sterling inspection; (2) Verrica's September 2021 statements about the complete response letter (CRL); (3) Verrica's November-December 2021 statements about "satisfactory resolution" of the problems at Sterling; and (4) Verrica's spring 2022 statements that continued to represent the issues at Sterling as resolved. The elements of falsity, materiality, and scienter are addressed below for each of these statements.

1. White's May-June 2021 Statements

(a) Falsity

"To state a valid securities fraud claim under Rule 10b–5, a plaintiff must first establish that defendant, in connection with the purchase or sale of a security, made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading." Oran v. Stafford, 226 F.3d 275, 282 (3d Cir. 2000) (quotation marks omitted). "[N]on-disclosure of material information will not give rise to liability under Rule 10b–5 unless the defendant had an affirmative duty to disclose that information." Id. at 285. A duty to disclose may arise if, among other reasons, there has been "an inaccurate, incomplete or misleading prior disclosure." Id. "[D]isclosure is not a rite of confession, and companies do not have a duty to

disclose uncharged, unadjudicated wrongdoing." City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG, 752 F.3d 173, 184 (2d Cir. 2014) (quotation marks and footnotes omitted).

Other than the misrepresentation of the timing of the Sterling inspection as being in the future (which is not alleged to be material), Plaintiff does not allege that any of White's May-June 2021 statements were literally false. Instead, Plaintiff argues that the statements were misleading because they implied that the Sterling inspection would not result in a delay of the approval of VP-102 when, in fact, problems had been uncovered that would prevent the FDA from accepting Verrica's application.

Specifically, White is alleged to have responded to a question raising concerns about whether the FDA's inspection of the Sterling facility could delay the approval of VP-102. At the time, the FDA had not explicitly told Verrica that the Sterling inspection would result in a denial, but it had told Sterling that the facility was out of compliance, and compliance was necessary for approval. Yet, despite this information, White told investors that "we'll have our inspections take place according to plan." Plaintiff asserts this falsely implied that the Sterling inspection was not about to present a major setback to VP-102's approval.

In response, Defendants argue that Plaintiff reads too much into White's May 19, 2021 statement that FDA inspections would go forward as planned, which Defendants assert addressed only a possible "backlog" that might prevent FDA inspectors from being "able to get into that facility or two facilities on time." (Am. Compl. ¶ 108.) Defendants also place substantial emphasis on case law holding that it is not per se misleading to conceal a Form 483 because the FDA uses that form to provide interim feedback rather than a final decision. E.g., Schaeffer, 2020 WL 7701463, at *8-9 (analyzing the materiality of a Form 483 in terms of its content and possible effect on approval).

Viewing the facts pled in the light most favorable to Plaintiff, I find that Plaintiff has sufficiently alleged falsity. White's statement that the FDA inspection of Sterling would go forward as planned could be read to suggest that White misleadingly concealed that the inspection had already occurred and would prevent the timely approval of VP-102. An analogy amplifies this point: Suppose a person offers a friend a ride to the airport on Saturday but notes they will need their car inspected first. If the mechanic calls to inform the person that the inspection is not finished but problems were found, and the person then tells the friend that they "fully anticipate having the car inspected by Saturday according to plan," this could misleadingly imply that the inspection would not present an obstacle to offering a ride to the airport as promised. Similarly, it is a plausible inference that White's statement misleadingly concealed that the Sterling inspection would inhibit, rather than facilitate, timely approval of VP-102.

A few additional allegations in the complaint warrant further discussion. First, while Plaintiff quotes the four problems identified in the FDA's Form 483 letter, the complaint provides little information about the severity of those problems or how difficult they would be for Sterling to fix. Cf. Schaeffer, 2020 WL 7701463, at *10 (noting that while observed cGMP violations "may have been quite serious," "extra facts" were needed to plausibly allege that the problems were not "eminently correctable" in time to avoid delaying approval). The complaint does allege, however, that a former employee recounted a discussion in a meeting that "receipt of the Form 483 would delay the launch of VP-102." (Am. Compl. ¶ 8.) That allegation raises an inference, plausible at this early stage of the proceedings, that the observed areas of non-compliance were serious enough to delay approval of VP-102. In addition, it is alleged that the FDA did ultimately deny approval of VP-102 based on cGMP violations at Sterling. While this hindsight fact would be unknown to Defendants in May-June 2021, it corroborates Plaintiff's claim that the four items identified in

May 2021 were serious. Thus, reading the complaint in the light most favorable to Plaintiff at the pleadings stage, it is reasonable to view the May 2021 inspection as a "failed" inspection that was a step backward in VP-102's approval.

While Defendants insist White was only addressing concerns of an administrative "backlog" that might delay the FDA's inspection, this is not the only plausible reading of White's statement. White was not discussing the timing of the FDA's inspection in a vacuum: he was discussing it in relation to the date (the "PDUFA date") by which FDA anticipated acting on Verrica's application for VP-102. It is a fair inference that a failed inspection would not be progress toward meeting that date. And the natural response to concerns of a backlog would have been to report that one inspection had already occurred, but White did not divulge this fact. Thus, White's statement that the FDA's inspections would go forward in a timely manner could be misleading by concealing that one inspection had occurred and this fact would frustrate rather than advance the goal of timely approval.[4]

Regarding Defendants' argument that it is not "per se" misleading to conceal a Form 483 because that form is used for interim feedback, it is plausible that the red flag raised in May 2021 was not that the FDA had used any particular form but that Sterling was not in cGMP compliance as required for approval of VP-102. Thus, it could be found that Defendants were under a duty not to falsely imply that the FDA's inspections were on track for a timely approval of VP-102 when this was not the case.

[4] In a footnote, Defendants contend that White's statement that the inspections would take place "according to plan" was "forward-looking," a characterization that could subject Plaintiff to a higher burden in pleading falsity. See 15 U.S.C. § 78u-5(c)(1). But Plaintiff is not complaining about White's prediction about when the inspection would occur, but, rather, his concealment of the fact that it had occurred and had found problems. Because that is a statement about past events, it is not subject to the rules for pleading forward-looking statements. Institutional Inv'rs Grp. v. Avaya, Inc., 564 F.3d 242, 255 (3d Cir. 2009).

For these reasons, Plaintiff has plausibly alleged that White's May-June 2021 statements falsely concealed problems with the May 2021 Sterling inspection that could delay the approval of VP-102.

(b) Materiality

Where a statement is misleading by omission, it is material if there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988).

Plaintiff alleges that VP-102 was Verrica's biggest product, that it could not go to market without FDA approval, and that approval could not be obtained if Sterling was not in cGMP compliance. Plaintiff asserts that a disclosure of the omitted fact would have revealed that Sterling was not in cGMP compliance. At this stage of the litigation, I find that it is plausible that this omission was material.

(c) Scienter

Scienter is "an intent to deceive, manipulate, or defraud, either knowingly or recklessly." In re Hertz Glob. Holdings Inc., 905 F.3d 106, 114 (3d Cir. 2018) (alterations and quotation marks omitted). Because Plaintiff has brought a securities fraud putative class action, the inference of scienter must be not merely plausible but "strong." 15 U.S.C. § 78u-4(b)(2)(A).

Plaintiff seeks to make out the strong inference of scienter in two ways: (1) by showing that White was aware of cGMP problems at Sterling at the time of his statements; and (2) by pointing to aspects of White's phrasing that suggest an intent to deceive.

Facts alleged in the complaint that could suggest White's knowledge of cGMP problems at Sterling include: (1) White was CEO, VP-102 was important to Verrica's business, and Sterling's cGMP compliance was important to the success of VP-102; (2) White spoke about the

Sterling inspection, suggesting he was aware of it; and (3) a former employee stated that White "was well aware of the receipt of the Form 483."

As to the first fact, it is a reasonable inference that White, as Verrica's CEO, would be aware of critical facts bearing on Verrica's "core business." In re Campbell Soup Co. Sec. Litig., 145 F. Supp. 2d 574, 599 (D.N.J. 2001) ("While asserting that defendants approved or helped prepare public disclosures is insufficient to establish knowledge of all aspects of the company's business, … knowledge may be imputed to individual defendants when the disclosures involve the company's core business."). The second fact, as well, could contribute to an inference that White was familiar with the Sterling inspection. Regarding the last fact, in assessing the strength of allegations from confidential sources, a court should evaluate the "detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." Institutional Invs. Grp. v. Avaya, Inc., 564 F.3d 242, 263 (3d Cir. 2009). Based on those factors, the allegations from Verrica's former employee are entitled to some weight, in that it is alleged that White and the former employee "got along well." However, I note that no other information is provided about the former employee's basis of knowledge.

Taken together, White's position as CEO, his comments on the Sterling inspection, and the facts pled regarding the former employee all contribute to an inference that, when White spoke in May-June 2021 about the inspection at Sterling, he was already aware that Sterling was not in cGMP compliance.

Next, Plaintiff points to ways in which White appeared to deliberately conceal information. White's choice to phrase the FDA's inspections in the future ("we'll have our inspections take

place according to plan") when one inspection had already occurred could suggest that White was dodging the question, raising an inference that he deliberately sought to avoid follow-up questions that could reveal problems. Similarly, when the truth came out in September 2021, Verrica's response could be read as covering up its prior lack of candor: Verrica's press release stated that "[a]t no time prior to the CRL was the Company notified by the FDA of any deficiencies at the CMO related specifically to the manufacturing of VP-102 or that their general investigation of the facility would have any impact on the Company's NDA." (Am. Compl. ¶ 69.) While the FDA itself had not told Verrica that problems at Sterling would impact the approval of VP-102, Verrica knew that they would, both because it knew that Sterling would have to be cGMP compliant for approval and because Verrica employees specifically discussed that the problems identified in the May Form 483 would delay approval of VP-102. (See Am. Compl. ¶ 8.) That Verrica allegedly acted to cover its tracks suggests an awareness that its prior statements were misleading.

Defendants argue that it is implausible that White would have lied about quality issues at Sterling in May 2021 and then, just months later, candidly revealed those same quality issues in a press release. As Plaintiff points out, though, the facts alleged could suggest that Verrica did not have much choice in September 2021: its investors allegedly knew that September 2021 was the anticipated date for the FDA to act on Verrica's application, and an explanation for the denial was therefore needed.

Defendants further object that Plaintiff has not alleged a motive for White to lie about problems at Sterling in May-June 2021. While motive is relevant, it is not the only way to establish scienter. Avaya, 564 F.3d at 276 ("Motive and opportunity may be useful indicators, but nowhere in the statute does it say that they are either necessary or sufficient."). Here, Plaintiff has pled

additional facts that, if true, could demonstrate White's awareness that his statements were misleading.

In summary, Verrica's alleged relationship with Sterling and White's role within Verrica provide a compelling reason to believe that White was aware of cGMP problems when he spoke, and White's alleged evasive phrasing, both in May 2021 and when problems occurred in September 2021, suggests an awareness that his statements were misleading. Based on these facts, I conclude that Plaintiff has raised the necessary "strong" inference of scienter.

2. Verrica's September 2021 Statements

Verrica's September 2021 press release was plausibly misleading in that it implied that Verrica had only recently become aware that quality problems at Sterling could impact the approval of VP-102. This could be proven to be false in that Verrica knew that Sterling had to be in cGMP compliance for approval, and Verrica employees had specifically discussed that the FDA's observations of cGMP problems would delay the approval of VP-102. Plaintiff's complaint also raises a strong inference that Defendants were aware of this misstatement because the error was patent. See In re Advanta Corp. Sec. Litig., 180 F.3d 525, 535 (3d Cir. 1999) (scienter may be inferred where misstatement is "so obvious that the actor must have been aware of it").

However, Plaintiff has not plausibly alleged that this misrepresentation in the September 2021 press release was material. The September 2021 press release candidly disclosed that there were quality problems at Sterling and that those problems had delayed the approval of VP-102. Plaintiff has not alleged that there was anything deficient about those disclosures, nor has Plaintiff explained how the timing of Verrica's knowledge would matter once it was known that Verrica's application had, in fact, been denied.

I will therefore grant Defendants' motion to dismiss as to Verrica's September 2021 press release for failure to plausibly allege that the alleged misstatement contained in it was material.

3. Verrica's November-December 2021 Statements

The complaint alleges that in November to December 2021, Verrica essentially announced that quality problems at Sterling had been "successfully resolved" and that Verrica had resubmitted its application for VP-102 on that basis. It is plausibly alleged that, in hindsight, these statements were materially false: the same quality problems allegedly persisted in February 2022, leading the FDA to deny Verrica's application a second time.[5] The issue is whether Plaintiff has raised the necessary "strong" inference that Defendants made these statements with scienter. I conclude that Plaintiff has not.

To show scienter, Plaintiff must raise a strong inference that Defendants recklessly disregarded the risk that the cGMP problems at Sterling had not, in fact, been resolved. But the complaint contains no allegations about Sterling's actions to address the problems observed in May 2021 or what Defendants knew about those actions—other than Verrica's September 2021 press release stating that Sterling "has implemented corrective actions to address the [FDA]'s concerns." (Am. Compl. ¶ 69.) The complaint therefore does not raise a strong inference that Defendants recklessly disregarded a risk that Sterling's corrective measures might be insufficient. See New York State Teachers' Ret. Sys. v. Fremont Gen. Corp., No. 07-cv-5756, 2009 WL 3112574, at *10 (C.D. Cal. Sept. 25, 2009) ("[T]he fact that subsequent disclosures revealed that the remedial measures were not sufficient does not render false the individual Defendants' contemporaneous statements about those measures").

[5] In a footnote, Defendants argue that the word "successful" is puffery. Puffery consists of "vague and general statements of optimism." Wallace v. Sys. & Computer Tech. Corp., No. 95-cv-6303, 1997 WL 602808, at *9 (E.D. Pa. Sept. 23, 1997). In context, the word "successful" in Verrica's announcement is susceptible to a reasonably definite meaning—namely, that Sterling was now in cGMP compliance such that VP-102 could be approved. The statement was therefore plausibly not puffery.

Plaintiff's briefing attempts to show that scienter has been sufficiently pled based on a supposition that Verrica treated Sterling's "voluntary action indicated" (VAI) classification by itself as successful resolution, irrespective of Sterling's corrective actions. Although Defendants do not entirely disavow that interpretation in their reply brief, the sufficiency of a complaint is measured by the allegations in it, and nowhere does the complaint suggest—much less raise the required "strong inference"—that Verrica uncritically assumed that the FDA's VAI classification meant that the quality issues at Sterling were resolved regardless of what steps Sterling might have taken to correct them.

For these reasons, I will grant Defendants' motion to dismiss as to Verrica's November-December 2021 statements for failure to raise a strong inference of scienter.

4. Verrica's Spring 2022 Statements

(a) Falsity

As alleged, some statements in Verrica's spring 2022 public filings were plausibly false: it was (plausibly) false to say on March 2 and May 9 that the quality issues at Sterling were "satisfactory[ily]" or "successful[ly]" resolved, because most of the same quality problems remained in February 2022. (Am. Compl. ¶¶ 121, 127.) Neither paragraph couched the successful resolution of Sterling's quality problems as Verrica's mere belief, and instead presented it as an established fact that Sterling's problems were, in fact, resolved. Plaintiff has plausibly alleged that these statements were false.

White's statements at the April 14 conference are different. To say that Sterling's quality problems were not related to VP-102 was technically true. While this statement could be misleading in isolation, in context it was truthful because White clarified in the next sentence that those quality problems did impact the approval of VP-102. (Am. Compl. ¶ 124.) And White's

statement that he was "very optimistic" is a "general statement[] of optimism" that cannot be materially false standing alone. In re Aetna Sec. Litig., 617 F.3d 272, 283 (3d Cir. 2010).

Finally, there is White's answer of "yes" to the question about whether investors should be "confident" in VP-102's approval:

> [Q.] … [G]iven that in the last review cycle, like you said the CRL issues were minor and not really associated with the actual product, I guess **we should feel pretty confident that we should see an approval here in late May**?
>
> [A.] From your lips to God's ears. **Yes**, I am very optimistic.

(Am. Compl. ¶ 125 (emphasis added).)

White's partial response "yes" could suggest that White had not received news inconsistent with approval in late May, which would contradict the FDA's findings in February 2022 that quality problems persisted. Although this is not the only plausible reading of White's statement, it is a plausible reading, and Plaintiff has therefore sufficiently alleged falsity as to this statement.

(b) Materiality

Materiality is satisfied as to these statements because the cGMP problems at Sterling resulted in the FDA denying approval of Verrica's biggest product.

(c) Scienter

Scienter hinges on whether Defendants knew or recklessly disregarded that the FDA's February 2022 inspection continued to show Sterling to be out of cGMP compliance. That, it turn, depends on whether Defendants knew about the February 2022 inspection and its outcome.

Plaintiff points to the following pled facts to support Defendants' knowledge: (1) Verrica knew that resolution of cGMP violations at Sterling was essential to obtaining approval for VP-102; (2) Verrica had a "Person in Plant" policy requiring Verrica personnel to be present at Sterling when VP-102 was manufactured; and (3) the FDA recommends that contract manufacturers such as Sterling communicate inspection observations to "owners" such as Verrica. But there is no

allegation that Defendants were aware that the FDA would be performing an inspection February 2022. It is also not alleged that Verrica's "Person in Plaint" policy applied to FDA inspections such as occurred in February 2022.

While Plaintiff's allegations might satisfy the plausibility standard, they are insufficiently detailed to qualify as "strong." Plaintiff provides little information about the nature of communications between Verrica and Sterling in February 2022. Unlike with May 2021, there is no interview by a former employee regarding the February 2022 inspection, nor did Verrica make public statements about it that could demonstrate Verrica's awareness. And it is not alleged that Verrica made the same preparations for the February 2022 inspection that it made for the May 2021 inspection—in fact there is no allegation that Verrica prepared for the February 2022 inspection in any way at all.

For these reasons, I will grant Defendants' motion to dismiss as to Verrica's spring 2022 statements for failure to raise a strong inference of scienter.

B. Loss Causation

A claim for securities fraud must satisfy two causation elements: "transaction causation" and "loss causation." McCabe v. Ernst & Young, LLP, 494 F.3d 418, 432 (3d Cir. 2007). Defendants here challenge only loss causation.

When a stock price is allegedly inflated by a misrepresentation and then declines, "loss causation" means that "the alleged misrepresentations proximately caused the decline in the security's value." Semerenko v. Cendant Corp., 223 F.3d 165, 185 (3d Cir. 2000). Thus, Plaintiff must plausibly allege that Defendants' misrepresentations implying a lack of problems with the FDA's inspection of Sterling proximately caused Verrica's stock to fall when Sterling announced the denial of its application for VP-102.

When the FDA inspected Sterling, it allegedly found violations of cGMP, and Sterling was required to be in compliance with cGMP for VP-102 to be approved. In addition, Plaintiffs have plausibly alleged that White's May-June 2021 statements concealed problems with the Sterling inspection to give the false impression that it would not present a barrier to approving VP-102. Verrica's stock price dropped when the September 2021 press release disclosed that Verrica's application for VP-102 had been denied due to Sterling being out of compliance with cGMP. These allegations plausibly make out a proximate causal link between the misrepresentations and the price drop and, therefore, sufficiently establish loss causation for purposes of a motion to dismiss.

Defendants nevertheless insist that loss causation is lacking because Verrica's September 2021 press release that led Verrica's stock price to fall did not disclose the same information that White allegedly concealed—namely, the issuance of a Forma 483. However, Plaintiff is not alleging that the Forma 483 in and of itself prevented VP-102's approval; rather Plaintiff contends that cGMP violations that were listed in the Form 483 were what led the FDA to deny Verrica's application. Verrica's September 2021 disclosure referenced the same cGMP violations that were communicated to Sterling in May 2021. While the September 2021 press release also revealed additional facts that were not known (and thus not concealed) in May 2021—such as that the denial of Verrica's application was by then a certainty rather than a mere possibility—at this stage it is plausible that the announcement conveyed the same essential information that White had concealed four months prior. See In re Urban Outfitters, Inc. Sec. Litig., 103 F. Supp. 3d 635, 655 (E.D. Pa. 2015) ("Although a corrective disclosure must be related to the same subject as the misrepresentation, and not some other adverse facts about the company, there is no requirement that the disclosure mirror the earlier misrepresentation.").

I will therefore deny Defendants' motion to dismiss with respect to loss causation.

C. Liability of Individual Defendants

The individual Defendants (White, Kohler, and Davis) assert that even if Plaintiff has sufficiently stated a claim against Verrica the corporation, the complaint should nonetheless be dismissed as to them because they are not personally responsible for the alleged misstatements. An individual may be liable for securities fraud in either of two ways: direct liability and "control person" liability, discussed below.

1. Direct Liability

An individual is directly liable for securities fraud if the elements of the tort are satisfied with respect to that individual. See Janus Capital Grp., Inc. v. First Derivative Traders, 564 U.S. 135, 142 (2011) (implied cause of action against one who "made" material misstatements). Plaintiff's brief in opposition to the motion to dismiss does not defend the sufficiency of direct liability as to Kohler and Davis. (See Brief in Opposition at 21 ("Defendants also complain that 'the [amended complaint] fails to make particularized factual allegations with respect to any of the Individual Defendants'…—ignoring the vast allegations which specifically implicate White.").) I will therefore grant Defendants' motion on direct liability as to those Defendants. The remaining discussion is limited to Defendant White and his May-June 2021 statements.

White personally made the May-June 2021 statements regarding inspections at Sterling. The elements of causation and materiality are also sufficiently alleged with respect to White for the reasons discussed above. As for scienter, Plaintiff offers the following allegations to suggest that White personally knew or recklessly disregarded that his statements were false: (1) White was CEO, VP-102 was important to Verrica's business, and Sterling's cGMP compliance was important to the success of VP-102; (2) White spoke about the Sterling inspection, implying he was aware of it; (3) a former employee stated that White "was well aware of the receipt of the Form 483"; and (4) White seemingly dodged a question about the Sterling investigation by

concealing that it had already taken place. Taken together, these alleged facts raise a strong inference that White was aware of the problems that the FDA had uncovered at Sterling in May 2021.

I will therefore deny Defendants' motion to dismiss as to White's direct liability for his May-June 2021 statements.

2. "Control Person" Liability

"Every person who, directly or indirectly, controls any person liable under" the securities laws "shall also be liable …, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a) [§ 20(a)]. "In addition to the statutory elements of controlling person liability, … in order for secondary liability to attach under § 20(a), the defendant must have been a 'culpable participant' in the act or acts constituting the violation or cause of action." Belmont v. MB Inv. Partners, Inc., 708 F.3d 470, 484 (3d Cir. 2013) (quotation marks omitted). Culpable participation requires knowledge of the fraud. Id.

As with direct liability, Plaintiff's brief in opposition to the motion to dismiss does not argue that Kohler and Davis were "culpable participants," and I will therefore grant the motion to dismiss as to them and limit the remaining discussion to White.

Plaintiff alleges that White controlled Verrica as its CEO, giving him direct authority over the company, and that he personally made many of the challenged statements, giving him control over those statements. His participation was plausibly "culpable" for the reasons stated above: there is a strong inference that White was aware of cGMP violations at Sterling when he made statements implying that the inspection at Sterling would proceed according to plan.

Plaintiff has therefore stated a claim for control-person liability against White as to White's May-June 2021 statements.

IV. CONCLUSION

For the reasons set out above, Defendant's motion to dismiss will be granted in part and denied in part. Because it is not clear that Plaintiff could not cure the deficiencies outlined above, Plaintiff will be given leave to amend, if Plaintiff can do so in good faith.

An appropriate order follows.